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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Thomas M. Jessell et al.

Serial No.: 09/654,462 Group Art Unit: 1632

Filed : September 1, 2000 Examiner: A-M Baker

For : GENETIC DEMONSTRATION OF REQUIREMENT FOR NKX6.1 AND NKX2.2 IN VENTRAL NEURON GENERATION

1185 Avenue of the Americas
New York, New York 10036
September 9, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

**COMMUNICATION IN RESPONSE TO JULY 9, 2002 RESTRICTION REQUIREMENT AND PETITION FOR ONE-MONTH EXTENSION OF TIME**

This Communication is submitted in response to the July 9, 2002 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the July 9, 2002 Office Action was originally due August 9, 2002. Applicants hereby petition for a one-month extension of time. The required fee for a one-month extension of time for a small entity is FIFTY FIVE DOLLARS ($55.00) and a check for this amount is enclosed. A response to the July 9, 2002 Office Action is now due September 9, 2002. Accordingly, this Communication is being timely filed.

In the Office Action, the Examiner restricted pending claims 1-12 to one of the following allegedly distinct inventions under 35 U.S.C. §121:

I. Claims 1-4, allegedly drawn to a method of converting a stem cell into a ventral neuron, classified in class 435, subclass 455; and

II. Claims 5-12, allegedly drawn to a method of diagnosing a motor neuron degenerative disease, classified in class 435, subclass 4.

The Examiner stated that inventions I and II are allegedly patentably distinct, one from the other, because the inventions are drawn to materially different methods that require different starting materials, different modes of operation, and produce different effects. The Examiner stated that the method of the invention of Group I requires as starting materials a stem cell and an Nkx6.1-encoding nucleic acid. The Examiner stated that the method of the invention of Group II requires as starting materials a nucleic acid sample from a subject and materials for sequencing a nucleic acid molecule. The Examiner stated that the method of the invention of Group I results in producing a ventral neuron, whereas the method of the invention of Group II results in a diagnosis of a subject. Thus, the Examiner stated that the method of the invention of Group I is patentably distinct from the method of the invention of Group II.

The Examiner stated that because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

In response to this restriction requirement, applicants' undersigned attorney, on behalf of applicants, hereby elects, with traverse, to prosecute the invention of Examiner's Group I, i.e. claims 1-4, allegedly drawn to a method of converting a stem cell

into a ventral neuron.

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicants request that the restriction of Examiner's Groups I-II from each other be withdrawn in view of the fact that the claims of Examiner's Groups I-II are not independent of each other. Applicants maintain that the claims of Examiner's Groups I-II do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group I, allegedly drawn to a method of converting a stem cell into a ventral neuron are related to the claims of Examiner's Group II in that the claims in both groups are related to methods which use the nucleic acid of homeodomain transcription factor Nkx6.1. The claims of Examiner's Group I relate to a method of converting a stem cell into a ventral neuron using the nucleic acid of homeodomain transcription factor Nkx6.1 and the claims of Examiner's Group II relate to a method of diagnosing a motor neuron degenerative disease using the nucleic acid of homeodomain transcription factor Nkx6.1. Therefore, the claims of Examiner's Groups I-II are related.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to Group I, allegedly drawn to a method of converting a stem cell into a ventral neuron using the nucleic acid of homeodomain transcription factor Nkx6.1 will reveal whether any prior art exists as to a method of diagnosing a motor neuron degenerative disease using the nucleic acid of homeodomain transcription factor Nkx6.1, since any such methods will include a method using the nucleic acid of homeodomain transcription factor Nkx6.1. Since there is no burden on the Examiner to examine Groups I-II in the subject application, the Examiner must examine the entire application on the merits.

Applicants maintain that claims 1-12 define a single inventive concept. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement and examine claims 1-12 on the merits.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee other than the enclosed $55.00 fee for a one-month extension of time is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

9/9/02
Date

John P. White
Reg. No. 28,678

John P. White
Registration No. 28,678
Attorney for Applicant(s)
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400